

K964083

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**510(k) Summary for Ultratherm 908i**

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**Predicate Device:** Ultratherm 808i

**Device Description:** The Ultratherm 908i is a shortwave diathermy device intended to generate deep heat in body tissues for the treatment of medical conditions such as the relief of pain, muscle spasms and joint contractures.

**Changes:** The labeling for the Ultratherm 908i limits its intended uses to those accepted by FDA for class II shortwave diathermy devices. Operating voltage and leakage are significantly reduced by replacing the tube generator with a compact transistor generator. The maximal effective output does not exceed 200 watts. The selected output is kept constantly in the scope of the patient's coupling conditions and is electronically indicated by the addition of a LED display and luminous band. Safety is enhanced by symmetrical and asymmetrical output sockets for the electrodes, the use of non-flammable silicon rubber field electrodes and sheltered coil field electrodes, and the reduction of impulse peak to 400 watts. Mechanical switches and a small light with a yes/no function have been replaced by touch sensitive contacts with LED control for the selection of operating mode and LED display of output intensity.

The foreign manufacturer of the Ultratherm 908i has independently marketed a similar device in Europe for 4 to 5 years and in Canada for 1 year. The same firm also manufactures the Ultratherm 808i which the present applicant distributes under a premarket notification (K862589) cleared by FDA on August 1, 1986. The safety, effectiveness, and reliability of the Ultratherm 908i have been established by the manufacturer's successful marketing of a similar device without the need for recall or receipt of significant adverse experience reports. The revised indications and changes in technological characteristics described in this present 510(k) submission enhance the safety and effectiveness of this device.